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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/682,161

07/30/2001

Frank Hetzel

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06/19/2006

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EXAMINER

MORGAN, ROBERT W

ART UNIT

PAPER NUMBER

3626

DATE MAILED: 06/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/682,161

Applicant(s)

HETZEL ET AL.

Examiner

Robert W. Morgan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 March 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 9-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 9-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Notice to Applicant

1. In the amendment filed 3/29/06, the following has occurred: claims 2-8 have canceled and claims 9-13 have been added. Now claims 1 and 9-13 are presented for examination.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1 and 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,991,731 to Colon et al. in view of "Base Ten Systems Completes Acquisition of Almedica Technology Group From Almedica International" by Business Wire.

As per claim 1, Colon et al. teaches a registration and sample ordering for the blinded, randomized testing of samples of a product at one or more sites, the system comprising:

- i) a remotely accessible electronic database (see: column 3, lines 14-23) programmed to:
 - a) run real-time or batch data processes (see: column 3, lines 29-31),
 - b) process at least two call flows (see: column 3, lines 14-23),
 - c) receive and process test subject registration data (see: column 9, lines 41-43),
 - d) randomize subjects (see: column 3, lines 14-23).

Colon fails to explicitly teach:

- e) determine when study numbers are fulfilled and thereafter lock out additional subjects;

and

ii) said database being linked to an interactive electronic ordering and tracking system for supplying samples to one or more sites, said ordering system having an electronic randomizing operation for randomizing and individualizing samples based on prior subject randomization.

However, Colon et al. teaches that the Internet network server computer (13, Fig. 1) executes the eligibility parameter of study and assigns patients to a particular study strategy according to clinical study protocol (see: column 6, lines 39-60). The Examiner considers the clinical study protocol to include the determination of a fulfilled study number so that prescriptions are not received which are outside the parameters of the study (column 6, lines 58-60). Therefore, it would have been obvious to include determining when study numbers are fulfilled and thereafter lock out additional subjects within the method and system for conducting clinical trials as taught by Colon et al. with the motivation of providing accurate records regarding the number participants involved a particular study thereby permitting precise and correct results to the study.

Colon et al. fails to also teach an interactive electronic ordering and tracking system for supplying samples to one or more sites, said ordering system having an electronic randomizing operation for randomizing.

Business Wire teaches Base Ten a fully integrated clinical supply chain management solution that includes inventory control, electronic batch records, manufacturing automation, trial design, labeling, packaging, randomization distribution and return management (see: paragraph 2). The Examiner considers the randomization distribution process to include an electronic randomizing operation for randomizing individual samples to one or more sites.

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One of ordinary skill in the art at the time the invention would have found it obvious to include Base Ten's clinical supply chain management system as taught by Business Wire within the method and system for conducting clinical trials as taught by Colon et al. with the motivation of serving customer more broadly, and helping them bring pharmaceutical products to market more quickly (see: Business Wire: paragraph 4).

As per claim 10, Colon teaches a randomization routine that assigns study patient to study medications using a random number generator and validated random assignment algorithms (see: column 5, lines 35-38).

Colon fails to teach the claimed electronic randomizing operation provides a virtual randomization system integrated with the electronic supply and shipping of samples.

Business Wire teaches Base Ten a fully integrated clinical supply chain management solution that includes inventory control, electronic batch records, manufacturing automation, trial design, labeling, packaging, randomization distribution and return management (see: paragraph 2). The Examiner considers the randomization distribution process to include an electronic randomizing operation for randomizing individual samples to one or more sites.

The motivation of combining the teachings of Business Wire within the system and method as taught by Colon et al. are discussed in the rejection of claim 1, and incorporated herein.

As per claim 11, Colon and Business Wire teaches a Database Management System (DMS) which is used to store study data for eligibility, randomization, follow-up, endpoint and management (see: Colon: column 3, lines 14-23).

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Colon and Business Wire fails to teach based on six different fixed flows comprising registration, open label, run-in, double blind, stratified and titration.

However these differences are only found in the non-functional data based on the different fixed flows. The different fixed flows comprising registration, open label, run-in, double blind, stratified and titration is not functionally related to the system for registration and sample ordering. Thus, this description material will not distinguish the claimed invention from the prior art in terms of patentability, *see Cf. In re Gulack*, 703 F.2d 1381, 1385, 217 USPQ 401, 404 (Fed. Cir. 1983); *In re Lowry*, 32 F.3d 1579, 32 USPQ2d 1031 (Fed. Cir. 1994).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to include different fixed flows because such data does not functionally relate to the system for registration and sample ordering and merely using different fixed flows from that in the prior art would have been obvious matter of design choice. *See In re Kuhle*, 526 F.2d 553, 555, 188 USPQ 7, 9 (CCPA 1975).

As per claim 12, Colon fails to teach the claimed locks out of additional enrollments when enrollment targets are reached.

However, Colon et al. teaches that the Internet network server computer (13, Fig. 1) executes the eligibility parameter of study and assigns patients to a particular study strategy according to clinical study protocol (see: column 6, lines 39-60). The Examiner considers the clinical study protocol to include lock out of additional enrollment when enrollment targets are reached so prescriptions are not received which are outside the parameters of the study (column 6, lines 58-60). Therefore, it would have been obvious to include locks out of additional enrollments within the method and system for conducting clinical trials as taught by Colon et al.

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with the motivation of providing accurate records regarding the number participants involved a particular study thereby permitting precise and correct results to the study.

4. Claims 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,991,731 to Colon et al. in view of "Base Ten Systems Completes Acquisition of Almedica Technology Group From Almedica International" by Business Wire as applied to claim 1 above, and further in view of "CB Technologies Signs Letter to Intent to Acquire UK-Based ClinPhone Group Limited" by PR Newswire.

As per claim 9, Colon and Business Wire teach a fully integrated clinical supply chain management solution that includes inventory control, electronic batch records, manufacturing automation, trial design, labeling, packaging, randomization distribution and return management (see: Business Wire: paragraph 2).

Colon and Business Wire fail to teach a voice recognition technology for placing orders.

PR Newswire teaches ClinPhone Group Limited that provides telephone interactive voice response (IVR) and Internet-based electronic data capture (EDC) system to manage clinical trials, including supply chain management for clinical trial supplies (see: paragraph 5).

One of ordinary skill in the art at the time the invention was made would have found it obvious to include the interactive voice response (IVR) technology as taught by PR Newswire with the system as taught by Colon and Business Wire with the motivation of allowing patient data to be collected, collated and distributed to client companies faster and more cost effectively (see: PR Newswire: paragraph 5).

5. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,991,731 to Colon et al. in view of "Base Ten Systems Completes Acquisition of Almedica

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Technology Group From Almedica International” by Business Wire as applied to claim 1 above, and further in view of U.S. Patent No. 7,054,823 to Briegs et al.

As per claim 13, Colon and Business Wire fails to teach the claimed ensures sites are approved for use, cuts off non-compliant sites, monitors site documentation and ensures appropriate filings have been made in all participating countries.

Briegs et al. teaches clinical trial management system that personnel and location sub-module used to identify and maintain information about locations that will be used for a study at the site (see: column 33, lines 23-26). Briegs et al. further teaches information is maintained to allow the assignment of the role of the location, identify whether or not the location is still active (see: column 33, lines 37-50).

One of ordinary skill in the art at the time the invention was made would have found it obvious to include information about clinical study site locations as taught by Briegs et al. within the system taught by Colon and Business Wire with the motivation of providing a system with the ability to easily modify a protocol to include new requirements and also tailor to meet country and site requirements (see: Briegs et al.: column 2, lines 5-9).

Response to Arguments

6. Applicant's arguments filed 3/29/06 have been fully considered but they are not persuasive. Applicant's arguments will be addressed hereinbelow in the order in which they appear in the response filed 3/29/06.

(A) In response to Applicant arguments, it is respectfully submits that the Examiner has applied new prior art to the newly added claims 9-13 at the present time. As such, Applicant's remarks with regard to the application of Colon and/or Business Wire to the newly added claims

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are moot in light of the inclusion of the teachings of PR Newswire and Briegs et al. addressed in the above Office Action.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

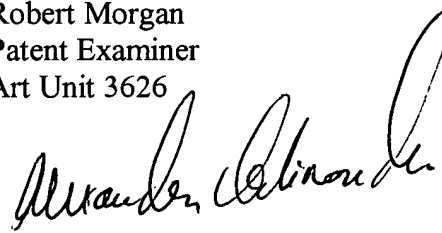
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert W. Morgan whose telephone number is (571) 272-6773. The examiner can normally be reached on 8:30 a.m. - 5:00 p.m. Mon - Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Thomas can be reached on (571) 272-6776. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

RWJ
Robert Morgan
Patent Examiner
Art Unit 3626



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